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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,287	03/28/2001	Young-Ro Byun	55761	6676

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EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/806,287

Applicant(s)

BYUN ET AL.

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Receipt of request for extension of time (granted) and amendment both filed 12-9-02 is acknowledged. Claims 1, 4, and 8 have been amended, claims 9-10 have been canceled and new claim 11 has been added as requested. Claims 1-8 and 11 are pending.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. **Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gr f et al (5,543,158; hereafter '158) in vi w of Rodg rs t al (5,534,261; hereaft r '261).**

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4. '158 teaches controlled release microsphere in which biodegradable polymer and the instant amphiphilic block copolymer are mixed and an active agent is incorporated into the microsphere. The ratios of biodegradable polymer/block copolymer and active agent/microsphere are within the instant ratios. These microspheres are not rapidly cleared from the blood stream by the macrophages of the reticuloendothelial system. '158 also teaches that biologically active molecules are contemplated to be delivered but does not teach that the active agent is retinoic acid.
5. '261 is relied upon for teaching controlled release microspheres made of polymers for controlled delivery of retinoids.
6. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to incorporate a retinoid into the formulation of '158 with the motivation of providing a delivery formulation for a retinoid that is not rapidly cleared from the blood stream by the macrophages of the reticuloendothelial system.

#### ***Response to Arguments***

7. Applicant's arguments filed 12-9-02 have been fully considered but they are not persuasive. Applicant argues that neither '158 nor '261 teach combination or mixture of the amphiphilic block copolymer with a biodegradable polymer. This argument is not found persuasive. '158 teaches mixing PLGA or PLA with the PLGA-PEG block polymer at column 13, lines 58-64. This mixing alters the half-life of microspheres made up of only the block polymer.

8. **Claims 1-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al (WO 97/15287; hereafter '287) in combination with Rodgers et al (5,534,261; hereafter '261) and further in combination with Lippman et al (1992).**

9. '287 teaches biodegradable polymeric microspheres that provide controlled release of an active agent. These microspheres comprise the instant amphiphilic block copolymer mixed with interferon- $\alpha$ . '287 does not teach delivery of retinoic acid with the instant microspheres.

10. '261 is relied upon for all that it teaches as stated previously.

11. Lippman is relied upon for teaching co-administration of interferon- $\alpha$  and 13-cis-retinoic acid for treatment of squamous cell carcinoma of the cervix.

12. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer retinoic acid in combination with the interferon- $\alpha$  of '287 with the motivation of providing a controlled release formulation for treating squamous cell carcinoma of the cervix.

### ***Response to Arguments***

13. Applicant's arguments filed 12-9-02 have been fully considered but they are not persuasive. Applicant argues that neither '287, '261 or Lippman et al teach combination or mixture of the amphiphilic block copolymer with a biodegradable polymer. This argument is not found persuasive. '287 teaches a peptide or protein drug (interferon- $\alpha$ ) intimately contained in a PLGA-PEG block polymer matrix. The peptide or protein drug (interferon- $\alpha$ ) meets the requirement of the biodegradable polymer limitation. Motivation

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for administration of a retinoid is provided by the combination of '261 and Lippman et al to provide a controlled release formulation for treating squamous cell carcinoma of the cervix.

**14. Claims 1-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al (5,665,428; hereafter '428) in combination with Rodgers et al (5,534,261; hereafter '261) and further in combination with Lippman et al (1992).**

15. '428 teaches biodegradable polymeric microspheres that provide controlled release of an active agent. These microspheres comprise the instant amphoteric block copolymer mixed with interferon. '428 does not teach delivery of retinoic acid with the instant microspheres.

16. '261 and Lippman are relied upon for all that they teach as stated previously.

17. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer retinoic acid in combination with the interferon- $\alpha$  of '428 with the motivation of providing a controlled release formulation for treating squamous cell carcinoma of the cervix.

### ***Response to Arguments***

18. Applicant's arguments filed 12-9-02 have been fully considered but they are not persuasive. Applicant argues that neither '428, '261 or Lippman et al teach combination or mixture of the amphiphilic block copolymer with a biodegradable polymer. This argument is not found persuasive. '428 teaches a peptide or protein drug (interferon)

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intimately contained in a PLGA-PEG block polymer matrix. The peptide or protein drug (interferon) meets the requirement of the biodegradable polymer limitation. Motivation for administration of a retinoid is provided by the combination of '261 and Lippman et al to provide a controlled release formulation for treating squamous cell carcinoma of the cervix.

### ***Conclusion***

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
March 8, 2003

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600